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09/763,983	02/28/2001	Tom Gilchrist	MUR-8564US	3635

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/763,983

Applicant(s)

GILCHRIST ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Specification*

This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 6, 8, 13, 15, 16, 18, 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "slow-release" in claim 1 (lines 3, 4, and 5) is a relative term which renders the claim indefinite. The term "slow-release" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

(ii) The phrase "slow release precipitant therefore" and "foaming thereof" in claim 1, (lines 4 and 6) is vague and indefinite, as it is confusing. Therefor what? Thereof what?

(iii) The phrase "and stabilizes the foamed form of the gelling agent" in claims 1 (lines 6-7) is vague and indefinite, as it is confusing. What other forms does the gelling agent take? It is always in a foamed form?

(iv) The phrases "derivatives of any of these" and "derivatives. . . thereof" in claims 3 (line 4), 4 (line 3), 15, (line 4), 16 (line 3) is vague and indefinite, as the metes and bounds of the claims are not properly set.

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(v) Claims 4 and 16 recite the limitation "as claimed in claim 3 (15) wherein said gelling agent is. . .carageenan gel" in line 3. There is insufficient antecedent basis for this limitation in the claim.

(vi) Regarding claims 8 and 20 (lines 3), the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

(vi) The phrase "in the form of a cured foam sheet" in claim 13 is vague and indefinite, as it is not clear what a cured foam sheet is, the specification does not define the phrase, and one of ordinary skill in the art would not be appraise of a cured foam sheet.

(vii) Claims 6 and 18 are rejected for the use of improper Markush groups. See MPEP 2173.05(h) for examples of proper conventional or alternative Markush-type language (e.g., ". . .selected from the group consisting of. . .and . . ."). Specifically, the alternative use of semi-colons and commas is confusing.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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Claims 1, 3-9, 12-13, 15-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Bakis et al. (5,851,461).

Bakis et al. teach a method of forming a polysaccharide foam from an aqueous solution of a polysaccharide, consisting essentially of a) forming an aqueous solution of a polysaccharide and a foam stabilizer; b) forming a wet foam; c) drying the wet foam with heated air to form a dried polysaccharide foam; d) cross linking the dried foam with di or trivalent cations; e) washing and then redrying the cross linked foam. Alginates, hyaluronates, hyaluronic acids, carrageenans, guar gums, and carboxymethyl celluloses are disclosed as polysaccharides. Calcium carbonate is disclosed as a divalent cation. Foaming agents, such as surfactants, are disclosed as being included in the aqueous solution of the invention to assist in foaming the solution. Deionized water is used to wash the gel. Air drying and convention hot air dryers are disclosed for the drying step. See Col. 2, line 40-Col. 5, line 2; Col. 8, line 15-Col. 18, line 55.

Claims 1, 3-5, 11-13, and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Comer et al. (3,962,482).

Comer et al. teach a composition comprising carageenan and potassium salt. Free organic acid is disclosed as being added to the composition. See abstract and Col. 13, line 29-Col. 14, line 50.

Claims 1-6, 9, 12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bannert (5,147,648).

Bannert teaches a method of improving the adhesiveness of gels to mucosae wherein one applies separately to the same area of a mucous membrane, two components capable of forming together one gel, wherein a metallic salt is one component and a polysaccharide is another

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component. The two components are disclosed as physically separate. Polysaccharides disclosed include alginic acid, polyguluronic acid, polymannuronic acid, propyleneglycol alginic acid, polygalacturonic acid. Salts disclosed include calcium salts. See Col. 1, line 22-Col. 6, line 67.

Claims 1-5, 9, 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Cole et al. (5,089,606).

Cole et al. teach water-insoluble polysaccharide hydrogel foam and a method and article of preparing a homogeneously foamed hydrogel from a two component aqueous system of water-soluble polysaccharides. One component comprises an aqueous suspension of di or trivalent metal salts. The other component comprising water soluble acid. At least one component contain a water-soluble polysaccharide. Polysaccharides disclosed include alginic acid, pectic acid, carrageenan, and others. Salts disclosed include calcium carbonate, calcium phosphate dibasic, barium carbonate, and zinc carbonate. See Col. 4, line 7-Col. 10, line 39 and Col. 18, line 20-Col. 22, line 20.

Claims 1, 3-6, 9, 11-13, 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Garbe et al. (EP 0 390 254).

Garbe teaches a form in place polysaccharide gel and a method of preparing the gel comprising mixing together two liquid components of a reactive two component system. One component is composed of a di or trivalent metal salt in aqueous solution of a polysaccharide, and another component is composed of water soluble acid. Alginate is disclosed as a polysaccharide and calcium carbonate, calcium phosphate dibasic, barium carbonate, and zinc carbonate are disclosed as salts. It is further disclosed that the invention may take the form of a

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closed bag divided into two compartments. Sterilizing the gel is disclosed. See Col. 2, line 15-Col. 9, line 50.

Claims 1, 3-8, 10, 12-13, 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilchrist et al. (WO 96/17595).

Gilchrist et al. teach foamable formulations and foam. Disclosed is a formulation comprising a) a closed container having a reservoir containing a foamable carrier and a reservoir containing an active ingredient; and b) a foaming means to produce a foam. A foaming agent is disclosed as an additive to the foamable carrier. Autoclaving is disclosed as a known method of sterilizing a gel. Gamma and e-beam radiation are disclosed as alternative means of sterilizing. Foamable carriers disclosed include alginate, carboxymethylcellulose, collagen, polysaccharides, agar, polyethylene oxides and others. Foaming agents disclosed include surfactant, cetrimide, lecithin, soaps, silicones, and the like. A formulation comprising alginate, cetrimide, and calcium and silver ion is disclosed, wherein the calcium released from the glass will stabilize the alginate by forming an insoluble calcium salt. See page 5, line 10-pg. 23, line 28.

Claims 1, 3, 5, 7, 8, 11-13, 15, 17 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Neumann (4,086,331).

Neumann teaches a gelatine-based composition and a method for the generation of stabilized foams therefrom. More specifically disclosed is a composition comprising gelatin, an anionic surface active agent, and a water soluble ferrous salt. See Col. 1, line 60-Col. 6, line 65.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakis et al. in view of Bannert, Cole et al., and Gilchrist et al.

Bakis et al. fail to teach separate packaging of precipitate and gelling agent, aluminum salts, organic acids, and the preferred method of sterilizing the gel (see above disclosure).

Bannert, Cole et al., and Gilchrist et al. are disclosed as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Bakis using the teachings of Bannert et al. and obtain a composition wherein the precipitant is packaged separately from the gelling agent because a) Bakis et al. and Bannert et al. both teach hydrogel foams comprised of polysaccharides and di or trivalent salts; b) both Bakis et al. and Bannert et al. teach alginate as a polysaccharide and calcium salts as di or trivalent salts; c) both teach the gels for medical use; d) Banner et al. teaches that the separation of the gelling agent and the precipitate and the subsequent application of each component onto the mucosa, results in a gel that more strongly adheres to the mucosa. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of the combined references using the teachings of Cole et al. and obtain a composition further comprising an organic acid because



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a) both the combined references and Cole et al. teach hydrogel foams comprised of polysaccharides and di or trivalent salts; b) both the combined references and Cole et al. teach alginate as a polysaccharides and calcium salts as di or trivalent salts; c) both teach the gels for medical use and both teach separation of the gelling agent (polysaccharide) from the precipitate (salt); d) Cole et al. teach that calcium carbonate, a salt disclosed for use by Bakis et al., reacts with a water-soluble acid to produce gases which become entrapped in the forming gel network, causing the formation of a stable hydrogel foam. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of the combined references using the teachings of Gilchrist et al. and obtain a process of sterilizing the gel comprising gamma irradiation because a) both the combined references and Gilchrist et al. teach hydrogel foams comprised of polysaccharides and di or trivalent salts; b) both the combined references and Gilchrist et al. teach alginate as a polysaccharides and calcium salts as di or trivalent salts; c) both teach the gels for medical use and Gilchrist et al. teach that sterilization is desirable where the foam is intended for medical use.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
August 29, 2001



DAMERON L. JONES  
PRIMARY EXAMINER